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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,409

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Reinhold Buck

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03/14/2011

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EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,409	<b>Applicant(s)</b> BUCK ET AL.	
	<b>Examiner</b> DIRK BASS	<b>Art Unit</b> 1777	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-15,29-31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-15,29-31,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's response filed January 6, 2011 is acknowledged. Claim 1 is amended, claim 8 is cancelled, and claim 34 is newly added. Claims 1-7, 9-15, 29-31, and 33-34 are pending and further considered on the merits.

#### ***Response to Amendment***

In response to applicant's amendment, the examiner maintains the grounds of rejection set forth in the office action dated February 23, 2010.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claim 34** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 34 recites that the membrane is uncharged. However, applicant's disclosure neither explicitly nor implicitly discloses a membrane, wherein said membrane is an uncharged membrane.

#### ***Claim Rejections - 35 USC § 102/103***

1. **Claims 1, 3-7, 9-10, 12-13, and 34** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al., USPA 2004/0167237 (Kim) as evidenced by Gorsuch et al., US 6802820 (Gorsuch).

Art Unit: 1777

2. Regarding claim 1, Kim discloses an asymmetric hollow fiber membrane (abstract, ¶ 0056) comprised of at least one hydrophobic polymer and at least one hydrophilic polymer (Example 1, ¶ 0188), wherein said membrane comprises a separation layer on the inner most layer of the hollow fiber membrane (REF a, fig. 1), wherein said membrane allows passage of molecules having a molecular weight of up to 45kD with a sieving coefficient of 0.1-1.0 in the presence of whole blood, wherein the membrane allows the retention of a portion of albumin in the presence of whole blood (Table 1, Example 1).

3. Kim is silent as to the molecular weight exclusion limit of about 200kD. Nevertheless, Kim discloses a hollow fiber membrane with the same preferred structure as contained in Applicant's claims/specification; therefore, it is inherent that said membrane has the molecular weight exclusion limit of about 200kD (See MPEP 2112).

4. In the alternative, molecular weight exclusion limits are deemed to be result effective variables as evidenced by Gorsuch (fig. 7). Gorsuch provides evidence in figure 7 that size exclusion limits can be easily manipulated based on the test methods used to determine the size exclusion limits and a multitude of possible structural and operational limitations can be envisaged based on these characteristics. Therefore, at the time of invention it would have been obvious to a routineer in the art to modify the molecular weight exclusion limit of Kim since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Section II, Part B).

5. Regarding claim 3, Kim discloses a membrane wherein said at least one hydrophobic polymer is present in an amount of 50-80% by weight (§ 0068-0071, 0138-0139).
6. Regarding claim 4, Kim discloses a membrane wherein said at least one hydrophilic polymer is present in an amount of 20-50% by weight (§ 0100, 0192).
7. Regarding claims 5 and 6, Kim discloses a membrane wherein the hydrophobic polymer is polysulfone (§ 0051) and the hydrophilic polymer is polyvinylpyrrolidone (§ 0040).
8. Regarding claim 7, Kim discloses a membrane wherein said membrane has a 3 layer asymmetric structure (fig. 1).
9. Regarding claim 9, Kim discloses a membrane wherein the separation layer has a thickness of less than 0.5  $\mu\text{m}$  (§ 0057).
10. Regarding claim 10, Kim discloses a membrane wherein the separation layer contains pore channels (§ 0056).
11. Regarding claim 12, Kim does not explicitly disclose the sieving coefficient for IL-6 in whole blood. However, Kim discloses a membrane that has a  $\beta$ 2 microglobulin (MW 11kD) sieving coefficient of 1 and  $\alpha$ 1 microglobulin (MW 33kD) sieving coefficient in the range of 0.16-.024. Therefore, it can be envisaged that IL-6 (MW 21kD) will have a sieving coefficient of at least 0.9.
12. Regarding claim 13, Kim discloses a membrane wherein the sieving coefficient for albumin in blood is below 0.05 (Table 1).

Art Unit: 1777

13. Regarding claim 34, Kim discloses a membrane wherein the membrane is an uncharged membrane (Comparative Examples 1-3).

14. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Deppisch et al., "Blood Material Interactions at the Surfaces of Membranes in Medical Applications" (Deppisch).

15. Kim fails to explicitly disclose the size of hydrophilic domains on the membrane surface are in the range of 20-50nm. However it is well known, as disclosed by Deppisch, that polyvinylpyrrolidone hemodialysis membranes such as those disclosed by Kim have hydrophilic domains in the range of 20-200 nm (Pg. 247, Col. 2, Para. 1) and that hydrophilic domains improve thrombogenicity (Pg. 248, col. 2, l. 1-4). Since, Deppisch recognizes hydrophilic domains as a result effective variable, it would have been obvious to a person having ordinary skill in the art to optimize the size of the domains as it has been held that it is not inventive to discover the optimum ranges by routine experimentation (MPEP 2144.05, Part II).

16. **Claims 11, 14-15, 29-31, and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Buck et al., US 4935141 (Buck) as evidenced by Gorsuch and Kagawa et al., EP 0568045 (Kagawa).

17. Regarding claims 11 and 29, Kim does not explicitly disclose the pore size in the separation layer. However, asymmetric hollow fiber membranes having pore sizes in the range of 20-40nm are well known in the art as disclosed by Buck. Buck teaches an asymmetric hollow fiber membrane (abstract and Claim 1) wherein the separation layer contains pore channels with a pore size of 20-40nm (Claim 2). Therefore, it can be

Art Unit: 1777

envisaged that the membrane disclosed in Kim would have a pore size in the separation layer of about 20-40nm since it has been shown in the prior art that such pore sizes are effective in separating low molecular weight species such as toxic mediators from blood during dialysis treatments.

18. Furthermore, while Kim does not explicitly disclose the pore size of the separation layer, it would have been obvious to a routineer in the art to control the pore size in order to effect a separation efficiency, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (MPEP 2144.05, Section II, Part A).

19. Regarding claims 14-15 and 33, Buck further discloses a membrane having an outer layer, different from the finger-like structure and this outer layer is equated with applicant's fourth layer, as evidenced by the similarities between fig. 1B of Buck and fig. 4 of applicant's specification. It is presumed that the structure of Buck has the stated properties of an outer surface including a pore size of 0.5 to 3 micron, alternatively it would have been obvious to produce a membrane with a outer layer pore size in the range of 0.5 to 3 micron based on the teachings of Buck which has the same sponge-like and finger-like structure of layers and the same inner layer pore size, as evidenced by Kagawa. Kagawa discloses that outer surface layer has micropores with a 0.1-0.5 micron average pore diameter (Pg. 10, Lines 44-51).

20. Regarding claims 30-31, it is either inherent or would have been obvious to produce an outer sponge layer with the property of pore density in the range of 20,000 to 100,000 pores per mm<sup>2</sup>, based on the similarity in structure of Buck as evidenced by

Art Unit: 1777

Kagawa. Kagawa discloses the process conditions can be modified to optimize the outer surface structure using a spinning process whereby hollow fiber membranes having many micropores of relatively large diameter in their outer surface can be readily obtained. Kagawa presents a finding that one of ordinary skill in the art could optimize the process conditions to obtain the desired pore size and number of pores on the surface with a reasonable expectation of success.

21. Alternatively, although Buck does not appear to expressly disclose that this outer layer is the fourth layer, it would have been obvious to one having ordinary skill in the art to include a fourth layer as it has been held that mere duplication of parts has no patentable significance (MPEP 2144.04, Part VI). Including four layers in a hollow fiber membrane is well-known, as evidenced by Gorsuch. Gorsuch discloses four zones in a hollow fiber membrane (Fig. 1). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

22. Applicant's arguments with respect to claim 1 have been considered but are not persuasive.

23. Applicants argue that since Kim tests the membrane in physiological saline rather than blood, the membrane of Kim would not comprise the molecular weight cut off values recited in claim 1. However, the examiner maintains that the membrane of Kim would encompass the cut off values recited in claim 1, since applicant has not described any functional differences between the claimed membrane and that of the prior art. The examiner considers the argument moot since the structural elements



recited in the claim are found in the prior art, which would envisage encompassing the same molecular weight cut off values.

24. Applicant argues that Kim's recited molecular weight cut off values do not correspond to the claimed molecular weight cut off values. In response, claim 1 requires a membrane which allows passage of molecules having a weight of up to 45 kD. The prior art membrane is shown to allow passage of molecules having a weight of up to 45 kD (Table 1). Therefore, the examiner maintains that Kim discloses this limitation recited in claim 1.

25. With respect to applicant's argument concerning the separation layer being the inner most layer of the membrane, the examiner reminds applicant that the language found in claim 1 does not preclude other separation layers from existing throughout the membrane. The limitation of claim 1 only requires that **a** separation layer exists in the inner most layer of the membrane.

26. Applicants continue to argue that the structure of Kim's membrane is different than that instantly claimed. However, applicants have failed to point out the recited **structural** differences between claim 1 and the prior art. The examiner considers the structural elements of claim 1 to be the composition of the membrane (hydrophobic polymer and hydrophilic polymer) and the molecular weight cut off. The remaining limitations have not been adequately described by structural components.

27. Concerning applicant's argument with respect to Gorsuch, the examiner maintains that it is routine to optimize size exclusion limits of membranes based on composition, pore size, mode of manufacture, or any of a plethora of other means.

***Conclusion***

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1777

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1777

/DRB/  
Dirk R. Bass